

### **REMARKS**

The Office action dated April 15, 2009 is acknowledged. Claims 1-30 are pending in the instant application. According to the Office action, each of claims 1-30 are rejected. By the present Office Action response, claims 1, 15, 17 and 24 have been amended and claim 10 has been canceled. Claim 1 has been amended to incorporate the subject matter of canceled claim 10. Claim 24 has been amended to clarify that ethanol is not another basic active agent but rather is the solvent. Claims 15 and 17 have been amended to clarify some informal antecedent basis issues. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

### **Objection to the Drawings**

The Examiner has objected to the drawings for various informalities. Enclosed herewith is a set of replacement drawings to replace those currently on file. Withdrawal of this objection is respectfully requested.

### **Rejection of Claims 1 – 30 under 35 U.S.C. 112, second paragraph**

Claims 1 – 30 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that the phrase “at least one of said at least one additional preparation containing at least one” in claim 1 is a range within a range and is thus indefinite. Claim 1 has been amended to clarify this wording. Withdrawal of the rejection is requested.

### **Rejection of Claims 1, 2, 5, 10, 12, 17, 22 and 23 under 35 U.S.C. 102(b)**

Claims 1, 2, 5, 10, 12, 17, 22 and 23 have been rejected under 35 U.S.C. 102(b) as

being anticipated by U.S. Patent No. 4,765,348 (Honeycutt). The Examiner states that Honeycutt teaches each and every limitation of the aforementioned claims. In particular, the Examiner states that Honeycutt teaches a device for administration of nicotine to the human body by inhalation for the purpose of being a non-combustible simulated cigarette, wherein the device comprises a first preparation containing a free base of nicotine containing in a polytetrafluoroethylene matrix and a second preparation containing a volatile acid, such as acetic acid, which is separated from the first preparation by an impermeable partition. The Examiner further states that the device contains a first air inlet, located to the right of section 18 in Figure 3, directing an inhaled airstream into an oblong air supply channel around section 18 in Figure 3, a common flow path 22 where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture to where the common flow path leads.

The Applicant respectfully disagrees with the Examiner's assessment of the presently claimed invention in view of Honeycutt. It is respectfully submitted that Honeycutt fails to disclose each and every limitation of the presently claimed invention as the claims are currently amended. In particular, the Applicants submit that Honeycutt teaches a non-combustible simulated cigarette inhaler device which includes a hollow cylindrical tube having an open air inlet and an opposed open air outlet. Two elements of absorbent air permeable material are located within the hollow tube. The first element of absorbent air permeable material is located across a segment of the transverse cross-sectional area of the tube and is impregnated with a nicotine-free base material. The other element of absorbent air permeable material is located across the remaining segment of the transverse cross-section of the tube, and is impregnated with an acid

which is reactive with the free base.

Honeycutt also teaches that the absorbent air permeable material may be cotton, i.e., consists of fibers or of particles of polytetrafluoroethylene. The absorbent air permeable material is impregnated with either the nicotine free base or the acid. The term “impregnated” means that the absorbent air permeable material is loaded with nicotine free base or acid(s) in that the nicotine free base or the acid(s) is/are present as liquid or is/are absorbed to the surface of the absorbent air permeable material. It is submitted that “impregnated” always means that the absorbent air permeable material is loaded with nicotine free base or acid(s) after (emphasis added) said material has been formed as elements for the inhaler, and that the nicotine base of the acid are not merged with the absorbent air permeable material. “Impregnated” does not mean that the basic active agent and/or the acid(s) are incorporated into the air permeable material as such.

To the contrary, the presently claimed invention provides that the nicotine base, basic active agent and/or the volatile acid are contained in the polymer matrix, preferably in dispersed or dissolved state. Therefore, the nicotine base, further basic active agent and/or the volatile acid are mixed with the polymer of the matrix prior to manufacturing the preparation. That is not the case with the impregnated absorbent air material of Honeycutt.

Upon use of the device of the present invention, air flows over the preparation consisting essentially of the polymer matrix and the nicotine base or the acid contained in the matrix (paragraph [000067]). The nicotine base and the acid are released from their matrices into the air stream.

Having the nicotine base, another basic active agent and/or the volatile acid is

incorporated into a polymer matrix (paragraphs [000028] – [000029]) rather than absorbed to the surface of a material. It is thus possible to increase the device's load with nicotine, other basic active agent and/or acid to provide a sustained release of nicotine base, basic active agent and volatile acid to the air flow such that the inhaler of the present invention simulates the nicotine acquisition occurring by smoking of a conventional cigarette in a significantly improved manner.

Still further, Honeycutt does not teach the incorporation of nicotine base or an acid into a polymer matrix for being released from the matrix to be inhalable after salt formulation.

In view of the above, the subject matter of proposed present claim 1 is not anticipated by Honeycutt since the reference fails to teach each and every limitation of the present claims. Therefore, Honeycutt clearly fails to teach or otherwise disclose every limitation of the present invention as set forth in the present claims and therefore fails to anticipate the present invention. Withdrawal of this rejection is respectfully requested.

**Rejection of Claims 3, 4, 6-9, 13-16, 18-21 and 24-30 Under 35 U.S.C. 103(a)**

Claims 3, 4, 9, 24, 25 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 4,284,089 (Ray). The Examiner argues in the Office action that Honeycutt fails to teach the preparations containing a solvent suitable for inhalation. However, the Examiner refers to Ray for teaching a preparation containing water as a solvent as well as menthol dissolved in ethanol as a flavoring. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler of Honeycutt with solvents as taught by Ray in

order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 6, 7, 8, 14, 26, 28 and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt. The Examiner argues that, regarding claim 6, Honeycutt teaches the chemical balance between volatized nicotine and acid can be controlled, but does not disclose the exact ratio of the chemical balance. However, the Examiner concludes that it would have been obvious to one skilled in the art that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

The Examiner also argues that, regarding claims 7, 8, 14, 26 and 30, Honeycutt discloses the claimed invention except for the inspiration duration, velocity, nicotine dose, particle size and negative pressure differential. The Examiner concludes that it would have been obvious to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claim 28 and 29, the Examiner has concluded that Honeycutt discloses the device having an impermeable part 24 as well as discloses that the device can be made of any material, but does not disclose a definite composition of the whole device. The Examiner concludes that it would have been obvious to make the entire device out of the impermeable material of impermeable partition 24 and for this material to be a polyester material coated with a copolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability

for the intended use as a matter of obvious design choice.

Claim 29 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 5,400,808 (Turner). The Examiner argues that Honeycutt does not disclose the material which is impermeable but that Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate. Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt of a material as taught by Turner to provide the advantage of a longer shelf life of the contents of the inhaler.

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 726,037 (Ferre). The Examiner argues that Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. The Examiner refers to Ferre for teaching an inhaler with separate impermeable compartments that have orifices that can be opened or closed. Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt with sealable compartments as taught by Ferre and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

Claims 15, 16 and 18-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 5,660,169 (Kallstrand). The Examiner argues that Honeycutt discloses the claimed invention except for a part formed by deep-drawing. The Examiner argues that Kallstrand discloses an inhaler device with an upper and bottom part containing a compartment with a peelable seal formed by deep-

drawing. Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt with deep-drawn components as taught by Kallstrand in order to provide the advantage of an inexpensive way to manufacture the device.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion set forth in the Office action for the numerous deficiencies of Honeycutt discussed above. As established above, Honeycutt fails to teach each and every limitation of the presently claimed invention. Moreover, none of the cited secondary references make up for any of the numerous deficiencies of Honeycutt. Therefore, the combination of Honeycutt with the teachings of the secondary references fails to teach every limitation recited in the present claims.

It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Honeycutt alone or in combination with the secondary references, nor would one skilled in the art be motivated to modify Honeycutt to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

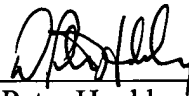
### Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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